

WHEREAS, on May 19, 2022, the Court entered the Scheduling Order (D.I. 29) for consolidated Case No. 22-1461-CFC (*i.e.*, Case Nos. 22-1461-CFC, 22-1462-CFC, 22-1465-CFC, and 22-1467-CFC; “this Action”);

WHEREAS, on August 10, 2023, the Court granted the “Stipulation and [Proposed] Order to Extend Time” (D.I. 65);

WHEREAS, on March 27, 2024, the Court granted the “Stipulation and [Proposed] Order to Extend Time” (D.I. 134) (together, with D.I. 29 and D.I. 65, “Schedule”);

WHEREAS, the Schedule includes limitations on the content and timing for service of Asserted Claims and Asserted Prior Art (*see, e.g.*, D.I. 29 ¶¶ 5, 7(a));

WHEREAS, Plaintiffs are currently asserting patents from the following patent families:

- Patents<sup>1</sup> that claim earliest priority to U.S. Provisional Patent Application No. 60/801,089, filed on May 16, 2006, and which according to the Orange Book expire in 2027 (“the 2027 Patent Family”);
- Patents<sup>2</sup> that claim earliest priority to U.S. Provisional Patent Application No. 60/914,288, filed on April 26, 2007, and which according to the Orange Book expire in 2028 (“the 2028 Patent Family”);
- Patents<sup>3</sup> that claim earliest priority to U.S. Provisional Patent Application No. 61/028,141, filed on February 12, 2008, and which according to the Orange Book expire in 2029 (“the 2029 Patent Family”);
- Patents<sup>4</sup> that claim earliest priority to U.S. Provisional Patent Application

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<sup>1</sup> Plaintiffs are currently asserting U.S. Patent Nos. 9,000,011; 9,987,263; 10,383,864 and 10,406,143 against Teva. Plaintiffs have not asserted and have covenanted not to sue Teva on U.S. Patent Nos. 9,480,682 and 11,241,422. Plaintiffs have not asserted any patents from the 2027 Patent Family against Aurobindo.

<sup>2</sup> Plaintiffs are currently asserting U.S. Patent No. 10,925,866 against Teva. Plaintiffs previously asserted but are no longer asserting U.S. Patent No. 9,999,618 against Teva. Plaintiffs have not asserted and have covenanted not to sue Teva on U.S. Patent No. 11,033,538. Plaintiffs have not asserted any patents from the 2028 Patent Family against Aurobindo.

<sup>3</sup> Plaintiffs are currently asserting U.S. Patent Nos. 10,813,921 and RE48,608 against Teva. Plaintiffs have not asserted and have covenanted not to sue Teva on U.S. Patent Nos. 8,592,362; 9,095,584. Plaintiffs have not asserted any patents from the 2029 Patent Family against Aurobindo.

<sup>4</sup> Plaintiffs are currently asserting U.S. Patent Nos. 10,806,727; 10,874,655; 11,278,540; 11,304,940; 11,357,762; 11,612,593; 11,612,594; and 11,633,387 against Defendants. Plaintiffs previously asserted but are no longer asserting U.S. Patent Nos. 10,792,279; 10,849,889; 10,849,890; 10,874,657; 11,278,536; 11,278,537; 11,278,538; 11,278,539; 11,357,761; 11,357,763; 11,357,764; 11,357,765; 11,376,244; 11,389,436; 11,389,437; 11,426,396; and 11,458,128 against Defendants. Plaintiffs have not asserted and have covenanted not to sue Defendants on U.S. Patent Nos. 10,251,873; 10,471,053; 10,525,045; 10,792,278; 10,799,491; 10,857,141; 10,857,142; and 10,874,656. Plaintiffs have indicated that they intend to assert U.S.

No. 62/512,458, filed on May 30, 2017, and which according to the Orange Book expire in 2038 (“the 2038 Patent Family”); and

- Patents<sup>5</sup> that claim earliest priority to U.S. Provisional Patent Application No. 62/512,458, filed on May 30, 2017, and which according to the Orange Book expire in 2039 (“the 2039A Patent Family”);

WHEREAS, collectively the 2027 Patent Family, 2028 Patent Family, 2029 Patent Family, 2038 Patent Family and 2039A Patent Family shall be referred to as the “Asserted OB Patent Families”;

WHEREAS, Plaintiffs have not and will not assert patents from the following patent family: Patents, including U.S. Patent No. 10,076,514 and 11,234,972, which claim earliest priority to U.S. Provisional Patent Application No. 62,311,511, filed on March 22, 2016, and which according to the Orange Book will expire in 2037 (“the 2037 Patent Family”);

WHEREAS, Plaintiffs previously asserted, but are no longer asserting and will not assert, patents from the following patent family: Patents, including U.S. Patent No. 11,357,784, which claim earliest priority to U.S. Provisional Patent Application No. 62/626,955, filed on February 6, 2018, and which according to the Orange Book will expire in 2039 (“the 2039B Patent Family”);

WHEREAS, collectively the 2037 Patent Family and 2039B Patent Family shall be referred to as the “Non-Asserted OB Patent Families”;

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Patent Nos. 11,786,516 and 11,813,255 against Defendants. Plaintiffs have not indicated that they intend to assert U.S. Patent No. 11,666,564 against Defendants.

<sup>5</sup> Plaintiffs are currently asserting U.S. Patent Nos. 11,622,962; 11,633,388; and 11,642,334 against Defendants. Plaintiffs have not indicated that they intend to assert U.S. Patent No. 11,826,360 against Defendants.

WHEREAS, collectively the Asserted OB Patent Families and the Non-Asserted OB Patent Families shall be referred to as the “Consolidated Case Families”;

WHEREAS, Plaintiffs intend to assert in this Action additional patents from the Consolidated Case Families that have issued since the entry of the Schedule (“Later-Issued Consolidated Patents”);

WHEREAS, Plaintiffs have obtained and listed in the Orange Book, but not asserted, U.S. Patent No. 11,833,164, which claims earliest priority to U.S. Provisional Patent Application No. 62/883,756, filed on August 7, 2019, and which according to the Orange Book will expire in 2042;

WHEREAS, Plaintiffs may obtain and list in the Orange Book additional U.S. Patents, which claim earliest priority to U.S. Provisional Patent Application No. 62/883,756, filed on August 7, 2019 (collectively, with U.S. Patent No. 11,833,164, “the 2042 Patents”);

WHEREAS, Plaintiffs may have or obtain additional patents related to migalastat that will not be listed in the Orange Book (“non-OB Listed Patents”);

WHEREAS, the timing for service of Asserted Claims and Asserted Prior Art in the Schedule does not address the Later-Issued Consolidated Patents, the 2042 Patents, or any non-OB Listed Patents;

WHEREAS, the parties seek to adjust the Schedule to allow for Later-Issued Consolidated Patents to be asserted and tried in a single trial that provides certainty as to the scope of the dispute between the parties;

WHEREAS, the parties seek to provide and obtain reasonable certainty as to the scope of the dispute between the parties regarding the 2042 Patents and any non-OB Listed Patents (collectively, “Non-Consolidated Patents”); and

WHEREAS, the parties seek to minimize the burden on themselves and the Court and ensure the just, timely, and efficient progression of this Action.

NOW THEREFORE, IT IS HEREBY STIPULATED AND AGREED by the parties that:

1. Within 30 days of a Later-Issued Consolidated Patent issuing, Plaintiffs will identify to Defendants any asserted claim(s) of that Later-Issued Consolidated Patent (“Newly Selected Consolidated Claim(s)”);

2. In view of ¶¶ 5 and 23 of D.I. 29, the parties agree that:

(a) Plaintiffs’ “Preliminary Disclosure of Asserted Claims” may include (i) no more than 32 claims from the 2038 Patent Family and the 2039A Patent Family (collectively, the “1462 Patents”); (ii) no more than 10 claims of any one patent and no more than 12 claims total from the 2042 Patents, and (iii) no more than 12 claims from the 2027 Patent Family, the 2028 Patent Family, and the 2029 Patent Family (collectively, the “1461 Patents”);

(b) Plaintiffs’ “Final Election of Asserted Claims” (item 22 in Schedule A of D.I. 29) may include (i) no more than five asserted claims from among the 10 claims identified for that patent in the Preliminary Disclosure of Asserted Claims and (ii) no more than a total of 16 claims from among the claims identified in the Preliminary Disclosure of Asserted Claims for the 1462 Patents; (iii) no more than 6 claims from among the claims identified in the Preliminary Disclosure of Asserted Claims for the 2042 Patents, and (iv) no more than a total of 6 claims from among the claims identified in the Preliminary Disclosure of Asserted Claims for the 1461 Patents;

(c) For any non-OB Listed Patents that Plaintiffs intend to assert against Defendants, at times agreed to by the parties or by Court Order, Plaintiffs shall serve Defendants with

- (i) preliminary disclosure of asserted claims, which may include no more than 10 claims of any one patent and no more than 12 claims total from such non-OB Listed Patents, collectively, and (ii) a final election of asserted claims, which may include no more than a total of 6 claims from among the claims identified in the preliminary disclosure of asserted claims pursuant to ¶ 2(c)(i);
- (d) The parties agree to engage in good faith negotiations as to limitations on the number of prior art references for the 2042 Patents and non-OB Listed Patents after Plaintiffs identify the asserted claims for those patents;
- (e) for the avoidance of doubt, nothing in this Stipulation precludes (i) Plaintiffs from seeking the Court's permission to include additional claims in its Final Election of Asserted Claims or (ii) Defendants from seeking the Court's permission to include additional references in its Final Election of Asserted Prior Art (item 21 in Schedule A of D.I. 29).

3. Plaintiffs will defer filing an amended complaint asserting the Later-Issued Consolidated Patents from which Plaintiffs identify Newly Selected Consolidated Claims until the deadline for Amending the Pleadings in the Scheduling Order (*e.g.*, item 19 in Schedule A of D.I. 29, including any amendments (*e.g.*, D.I. 134) thereto (“No. 19”); “Final Amended Consolidated Complaint”);

4. One time and no later than 30 days before No. 19, Plaintiffs may supplement their Preliminary Disclosure of Asserted Claims without good cause by addition and/or substitution of claims of (i) the 1461 Patents wherein no more than two (2) previously identified claims may be substituted, and (ii) for the 1462 Patents wherein no more than four (4) previously identified claims may be substituted;

5. One time and no later than 30 days after No. 19, Defendants may supplement their Preliminary Disclosure of Prior Art references without good cause by addition and/or substitution of prior art references of (i) the 1461 Patents wherein no more than two (2) previously identified prior art references may be substituted, and for the 1462 Patents wherein no more than four (4) previously identified prior art may be substituted.

6. For the parties respective Final Election of Asserted Claims (item 22 in Schedule A of D.I. 29) and Final Election of Asserted Prior Art (item 21 in Schedule A of D.I. 29), Plaintiffs shall make their Final Election of Asserted Claims before Defendants shall make their Final Election of Asserted Prior Art, and Defendants' Amended Final Election of Asserted Prior Art (item 23 in Schedule A of D.I. 29) will be stricken as moot.

7. Any Later-Issued Consolidated Patent that has issued as of No. 19 shall either be asserted in the Final Amended Consolidated Complaint or Plaintiffs shall provide Defendants with a covenant not to sue with respect to any such patent(s);

8. Plaintiffs shall provide Defendants with a covenant not to sue with respect to any other Later-Issued Consolidated Patent that issues after the filing of the Final Amended Consolidated Complaint;

9. For any Non-Consolidated Patents that have issued as of No. 19, Plaintiffs shall— as of No. 19—either assert the patent(s) in lawsuit(s) to be filed in the District Court for the District of Delaware (“Paragraph 9 Suit(s)”), or provide Defendants with a covenant not to sue with respect to any such patent(s);

10. For any Non-Consolidated Patents that issue after No. 19, Plaintiffs shall— within 21 days of said Non-Consolidated Patent(s) issuing—either assert the patent(s) in a Paragraph 9 Suit(s) or provide Defendants with a covenant not to sue with respect to any such patent(s);

11. The parties agree to engage in good faith negotiations as to whether or not any Paragraph 9 Suit(s) should be consolidated with this Action; for the avoidance of doubt, nothing in this Stipulation (a) constitutes agreement or acquiescence by any party that any Paragraph 9 Suit(s) should or should not be consolidated with this Action or (b) prevents any party from seeking or opposing consolidation of any Paragraph 9 Suit(s) with this Action;

12. Defendants will not file any pleading responding to an allegation relating to any Later-Issued Consolidated Patent until required to respond to the Final Amended Consolidated Complaint;

13. The parties will defer serving Infringement, Noninfringement, and Invalidity Contentions responding to allegations relating to any Newly Selected Consolidated Claims from any Later-Issued Consolidated Patent until the final deadline for service of Supplemental Infringement, Noninfringement, and Invalidity Contentions in the Scheduling Order (*i.e.*, items 26 and 27 in Exhibit A of D.I. 29, including any amendments thereto); and

14. The parties will not object to discovery related to the Newly Selected Consolidated Claims on the basis that the Later-Issued Consolidated Patents are not included in Pleadings as of the date the discovery is sought.



DATED: April 11, 2024

By:

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**IT IS SO ORDERED** this \_\_\_\_ day of \_\_\_\_\_, 2024.

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The Honorable Christopher J. Burke  
United States Magistrate Judge